

Office Action Summary	Application No.	Applicant(s)	
	10/665,514	HAURI ET AL.	
	Examiner	Art Unit	
	CATHERINE N. WITCZAK	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-33,35-42,44-50 and 52-55 is/are rejected.
- 7) ☐ Claim(s) 34,43 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20110926</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/13/11 has been entered.

Claim Objections

Claim 50 is objected to because of the following informalities: claim 50 claims dependency from cancelled claims 24. Appropriate correction is required. It appears that claims 50 was meant to claims dependency from newly added claim 46, and thus for the purposes of examination of the current office action, Examiner has treated the claim as such.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 29-31, 36, 46-48, and 53-55 are rejected under 35 U.S.C. 102(e) as being unpatentable over Crawford et al (US 2002/0161336A1) as modified by Burns (US 5,445,619)

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Crawford discloses a safety apparatus in Figures 1-14 comprising a needle hub 60 having a proximal portion and a distal portion, a needle 40 extending from a distal end of said needle hub; a collar 90 mounted directly on the distal portion of said needle hub, said collar having a first engage mechanism 97 at its inner circumferential surface; a housing 140 pivotally connected to said collar; and a needle sheath 50 having a proximal portion with a second engage mechanism 56 at its outer circumferential surface, said first and second engage mechanism fitted to each other when said sheath is fitted to said collar, said proximal portion having only one side in contact engagement to said collar for covering said needle extending from the distal end of said needle hub and said sheath is not in contact with said needle hub when said sheath is fitted to said collar and said first and second engage mechanism are engaged to each other.

With respect to claims 30 and 47, see figure 12.

With respect to claims 31 and 48, wherein second engage mechanism 56 comprises a groove and first engage mechanism 97 comprises a rib, see figures 2, 9, and 10.

With respect to claims 36 and 53, wherein the collar has a lock mechanism 118 and wherein the housing has another lock mechanism 194 for cooperating to fixedly retain the housing.

Crawford et al disclose the claimed invention except for the collar being rotatably mounted on the needle hub. Burns discloses in Figure 1 that it is known to use a collar 50 which is rotatably mounted on a needle hub 20, see also column 4, lines 19-20. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Crawford et al with a rotatably mounted collar as taught by Burns since the inclusion of a collar which can later be mounted on the hub imposes less requirements on the manufacturing process of the assembly, and also allows the collar safety assembly to be used on most standard fluid handling devices (see column 3, lines 20-22).

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2. Claims 32 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Burns as applied to claims 29 and 46 and further in view of Johnson (US 2002/0010433).

The Crawford reference as modified by Burns discloses the claimed invention except for a ring spaced around the hub end for a user to grasp. The Johnson reference teaches a ring spaced around a hub end for a user to grasp (Figures 2a-e). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Johnson in the apparatus and method of Crawford as modified by Burns in order to facilitate connection of the hub and barrel.

3. Claims 33 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Burns in further view of Johnson as applied to claims 32 and 49 and further in view of Pressly, Sr. et al (US 7,014,622).

Even though Crawford as modified by Burns do not explicitly disclose a window attention is directed to Pressly, Sr. et al. The Pressly, Sr. et al reference teaches the use of a window as a transparent ring on a needle assembly for viewing a joint of the needle hub, see Figure 10 and column 7 lines 35-43, wherein the transparency would be deemed a window. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Crawford as modified by Burns in view of Pressly, Sr. et al in order to provide a window via a transparent ring in order to see if the device has been properly connected.

4. Claims 35 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Burns as applied to claims 29 and 46 and further in view of Landis (US 5,490,841).

The Crawford reference as modified by Burns discloses the claimed invention except for overlapping housing lips with off-centered openings. Landis teaches the use of overlapping housing lips with off-centered opening in figures 9A-B and 11. It would have been obvious to one of ordinary skill in

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the art at the time of the invention to use the teachings of Landis in the apparatus and method of Crawford as modified by Burns in order to easily entrap the needle within the housing.

5. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Burns as applied to claims 29 and 46 and further in view of Gyure (US 5,669,889).

The Crawford reference as modified by Burns discloses the claimed invention except for lock mechanisms on the collar and housing utilizing an aperture. The Gyure reference teaches lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar (elements 61 and 57, Figure 3). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure in the apparatus of Crawford as modified by Burns in order to provide a lock mechanism for one-way safety locking to prevent re-exposure of the needle after covering.

6. Claims 38-42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (US 2002/10010433) in view of Crawford et al as modified by Burns and further in view of Pressly, Sr. et al.

The Johnson reference discloses a needle hub with a luer connector 68 and a ring 42 graspable by a user to remove the needle hub from a syringe surrounding, in a spaced relation, to the luer connector, see Figures 2A-F. Now even though Johnson does not explicitly disclose a collar and a needle sheath attention is directed to Crawford as modified by Burns. The Crawford reference teaches a needle hub 60 having a luer connector and a needle 40 on the distal end of the hub; a collar 90 having a housing 140 pivotally connected thereto directly fitted to and rotatable about said distal portion of the needle hub, and a needle sheath 50 having a proximal portion with only one side in contact engagement to said collar, said needle sheath not in contact with said needle hub and removable from said collar to expose said needle for use. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Johnson with the teachings of Crawford as modified by Burns in order to provide a

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shielding apparatus to help prevent accidental punctures by the needle. Now even though Johnson does not explicitly disclose a window in the ring, attention is directed to Pressly, Sr. et al. The Pressly, Sr. et al reference teaches the use of a window as a transparent ring on a needle assembly for viewing a joint of the needle hub, see Figure 10 and column 7 lines 35- 43, wherein the transparency would be deemed a window. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Johnson in view of Pressly, Sr. et al in order to provide a window via a transparent ring in order to see if the device has been properly connected. Also see rejection above with respect to Crawford as modified by Burns.

7. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (in view of Crawford et al as modified by Burns in view of Pressly, Sr. et al as applied to claim 38 and further in view of Landis.

The Johnson in view of Crawford as modified by Burns reference discloses the claimed invention except for overlapping housing lips with off-centered openings. Landis teaches the use of overlapping housing lips with off-centered openings in Figures 9A-B and 11. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus in order to easily entrap the needle with the housing.

Allowable Subject Matter

Claims 34, 43 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

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Applicant's arguments, see Remarks, filed 9/13/11, with respect to the disqualification of the rejection(s) of claim(s) under Hudon, based on the disqualification of the Hudon reference as prior art under 35 USC 103(c) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Burns.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witczak/
Examiner, Art Unit 3767
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Supervisory Patent Examiner, Art Unit 3767